NOTICE OF PUBLIC WORKSHOP

Intent to Adopt Regulations

NOTICE IS HEREBY GIVEN that the State Health Division will hold public workshops to consider amendments to Nevada Administrative Code (NAC) 449. The Carson City workshop is scheduled to begin at 9:00 a.m., Wednesday, September 30, 2009, at The Nevada State Health Division, 4150 Technology Way, Suite 303, Carson City, Nevada. The Las Vegas workshop is scheduled to begin at 1:00 p.m., Monday, September 28, 2009, at The Grant Sawyer Building, 555 E. Washington Ave., Suite #4412, Las Vegas, Nevada. These workshops will be conducted in accordance with NRS 241.020, Nevada's Open Meeting Law.

AGENDA

- 1. Introduction of workshop process
- 2. Public comment on proposed amendments of NAC 449. Surgical Centers for Ambulatory Patients
- 3. Public comment on proposed amendments of LCB File No. R096-08 Surgical Centers of Ambulatory Patients
- 4. Public comment on proposed amendments of NAC 449 General Requirements for Licensure
- 5. Public comment on proposed amendments of NAC 449.013 Fees
- 6. Public comment on proposed amendments of NAC 449 Outpatient Settings

Surgical Centers for Ambulatory Patients

The proposed changes will revise Chapter 449 of the Nevada Administrative Code and LCB File No. R096-08 to address the following: These regulation changes are being proposed in accordance with Assembly Bill 123, of the 2009 legislative session and to clarify certain requirements for ambulatory surgery centers. These regulatory changes will provide specific requirements for ambulatory surgery centers, to increase the quality of care provided in these healthcare settings. The immediate effect would be for Surgical Centers for Ambulatory Patients to become accredited by an accrediting organization approved by the Division. The changes will improve quality of care, protect patient safety. These amendments establish new fees that will offset the cost of the workload. The proposed changes are located at NAC 449.013.

General Requirements for Licensure

These regulation changes are being proposed in accordance with Assembly Bill 123, of the 2009 legislative session concerning licensure requirements for outpatient settings by providing the framework for application and permitting of outpatient settings. There will be additional cost to the Health Division associated with these regulatory changes, as yet, not calculated. The changes will require programming changes to the database in order to accommodate a "permit" for the new facility type, the current database only has the ability to issue "licenses". A change will also be necessary to accommodate the non-standard expiration dates for the permit holders, the current database expires all licenses on December 31st of each year. The permits will expire one year from the date of issuance. A portion of the fees collected in accordance with outpatient setting applications will go to accommodate database changes associated with these regulations.

Fees

The proposed changes will revise Chapter 449 of the Nevada Administrative Code to address the following: These regulation changes are being proposed in accordance with Assembly Bill 123, of the 2009 legislative session and the Governor's approved budget for the 2010 -2011 biennium concerning licensure requirements for outpatient settings and the periodicity of surveys for

ambulatory surgery centers and outpatient settings. They require facility fees to offset the cost of annual survey workload for ambulatory surgery centers and outpatient settings. The cost for licensure of ambulatory surgery centers is doubled. The fees collected will enable Health Division staff to conduct annual surveys to ensure good infection control practices and ensure the protection of public health.

Outpatient Settings

The proposed changes will revise Chapter 449 of the Nevada Administrative Code to address the following: These regulations are being proposed in accordance with Assembly Bill 123, of the 2009 legislative session to establish requirements for outpatient settings. These regulations will require previously unregulated facilities to have oversight by two entities, 1) an accrediting organization and 2) the Health Division. Oversight and regulation has associated costs. These regulatory changes will provide specific requirements for outpatient settings, to increase the quality of care and safety of patients receiving services in outpatient settings. The immediate effect is the cost of applying for a permit and for accreditation. The long term effect should result in future public confidence in the outpatient setting and along with credibility of the same. There will be a benefit to improve the quality of care, and protect patient safety. A fiscal note was attached to the AB 123 legislation during the session that estimated the \$257,236 for the 2009-2010 fiscal year and \$442,403 for the 2010-2011 fiscal year. The fees regulations will be modified to include outpatient setting and to establish new fees. These amendments establish new fees that will offset the cost of the workload. The proposed changes are sited at NAC 449.013.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two typed, 8 1/2" X 11" pages must submit the material to Shirley Rains, Administrative Assistant IV, no later than September 18, 2009, at the following address:

Bureau of Health Care Quality and Compliance 1550 E. College Parkway Suite 158 Carson City NV 89706 (775) 687-6588 (FAX)

Members of the public who require special accommodations or assistance at the workshops are required to notify Shirley Rains, AA IV, in writing at the Bureau of Health Care Quality and Compliance, 1550 E. College Parkway, Suite 158, Carson City, Nevada 89706, or by calling (775) 687-4475 no later than September 18, 2009.

Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow the Board members adequate time to review the documents.

A copy of the notice and the proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Bureau of Health Care Quality and Compliance 1550 E. College Parkway Suite 158 Carson City NV

Bureau of Health Care Quality and Compliance 4220 S. Maryland Parkway Suite 810 Bldg D Las Vegas NV

Nevada State Library and Archives 100 Stewart Carson City NV A copy of this notice has been posted at the workshop locations as well as the Nevada State Health Division website: http://www.health.nv.gov/Calendar.htm, the Southern Nevada Health District, 625 Shadow Lane, Las Vegas, Nevada and the Washoe County District Health Department, 1001 East 9th Street, Reno, Nevada.

Copies may be obtained in person, by mail, or by calling (775) 687-4475.

Copies may also be obtained from any of the public libraries listed below:

Carson City Library 900 North Roop Street Carson City NV 89702

Clark County District Library 833 Las Vegas Boulevard North Las Vegas NV 89101

Elko County Library 720 Court Street Elko NV 89801

Eureka Branch Library 210 South Monroe Steet Eureka NV 89316-0283

Humboldt County Library 85 East 5th Street Winnemucca NV 89445-3095

Lincoln County Library 93 Maine Street Pioche NV 89043-0330

Mineral County Library 110 1st Street Hawthorne NV 89415-1390

Pershing County Library 1125 Central Avenue Lovelock NV 89419-0781

Tonopah Public Library 167 Central Street Tonopah NV 89049-0449

White Pine County Library 950 Campton St. Ely NV 89301-1965 Churchill County Library 553 S. Main Street Fallon NV 89406

Douglas County Library 1625 Library Lane Minden NV 89423

Esmeralda County Library Corner of Crook and 4th Street Goldfield NV 89013-0484

Henderson District Public Library 280 South Water Street Henderson NV 89105

Lander County Library 625 S Broad Street Battle Mountain NV 89820-0141

Lyon County Library 20 Nevin Way Yerington NV 89447-2399

Pahrump Library District 701 East Street Pahrump NV 89041-0578

Storey County Library 95 South R Street Virginia City NV 89440-0014

Washoe County Library 301 South Center St. Reno NV 89505-2151 Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

MICHAEL J. WILLDEN Director



RICHARD WHITLEY, M.S. Administrator

TRACEY D. GREEN, M.D. State Health Officer

STATE OF NEVADA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH DIVISION

BUREAU OF HEALTH CARE QUALITY AND COMPLIANCE

Health Facilities/Lab Services 1550 College Parkway Suite 158 Carson City, Nevada 89706 (775) 687-4475 Fax: (775) 687-6588

Health Facilities/Lab Services 4220 S. Maryland Parkway Suite 810, Building D Las Vegas, Nevada 89119 (702) 486-6515 Fax: (702) 486-6520

Radiological Health
4150 Technology Way
Suite 300
Carson City, Nevada 89706
(775) 687-7550
Fax: (775) 687-7552

Radiological Health
2080 E. Flarningo
Suite 319
Las Vegas, Nevada 89119
(702) 486-5280
Fax: (702) 486-5024

September 1, 2009

Dear Owner/Administrator:

The 1999 legislature amended Nevada Revised Statutes (NRS) Chapter 233B to require that state agencies assess the impact of regulation changes or development on small businesses. A small business is defined in statute as "a business conducted for profit which employs fewer than 150 full-time or part-time employees" (NRS 233B.0382).

The Bureau of Health Care Quality and Compliance (BHCQC) are in the process of revising the Nevada Administrative Code (NAC), Chapter 449 for Surgical Centers for Ambulatory Patients. The proposed changes will revise Chapter 449 of the Nevada Administrative Code and LCB File No. R096-08 to address the following: These regulation changes are being proposed in accordance with Assembly Bill 123, of the 2009 legislative session and to clarify certain requirements for Surgical Centers for Ambulatory Patients. These regulatory changes will provide specific requirements for Surgical Centers for Ambulatory Patients, to increase the quality of care provided in these healthcare settings. The immediate effect would be for Surgical Centers for Ambulatory Patients to become accredited by an accrediting organization approved by the Health Division. The changes will improve quality of care and protect patient safety.

In order that we may determine the impact that these regulations will have on you as a small business, it will be necessary for BHCQC to gather certain information about your facility. If it is determined that the proposed regulations are likely to impose a direct and significant economic burden on small businesses, a small business impact statement will be provided at public workshops to be held prior to presenting the new regulations to the Board of Health. A questionnaire is enclosed with this letter so that we may document the information required to accomplish the impact statement. **Please respond to the questions no later than September 21, 2009.** You may mail or FAX the completed form to Paul Shubert, Health Facilities Surveyor IV, Bureau of Health Care Quality and Compliance, 4220 S. Maryland Parkway, Suite 810, Bldg. D, Las Vegas, Nevada 89119. FAX (702) 486-6520.

If you have further questions regarding this matter, please do not hesitate to call Mr. Shubert at (702) 486-6515.

Sincerely.

Shirley Rains, Administrative Assistant IV For Paul Shubert, Health Facilities Surveyor IV

Encl.

Public Health: Working for a Safer and Healthier Nevada

Small Business Impact Questionnaire

Surgical Centers for Ambulatory Patients

The following questions pertain to how the changes in the Nevada Administrative Code presented in the enclosure will affect your business. If it is determined that the proposed regulation is likely to impose a direct and significant economic burden upon a small business; or directly restrict the formation, operation or expansion of a small business; then the agency will take any or all of the following actions:

- 1. Insofar as practicable, consult with owners and officers of affected small businesses.
- 2. Consider methods to reduce the impact of the proposed regulation, and
- 3. Prepare a small business impact statement and make copies of the statement available to the public at the workshop conducted and the public hearing held pursuant to NRS 233B.061.

Please answer each of the questions that apply and add any qualifying remarks that may help us to understand your position. Mail or FAX your completed form, no later than September 21, 2009, to:

Paul Shubert, HFS IV Bureau of Health Care Quality and Compliance 4220 S. Maryland Parkway, Suite 810, Bldg. D Las Vegas, NV 89119 FAX (702)-486-6520

business mployees.

If more than 150, you will not need to answer the rest of the questions. Please FAX questionnaire to the above address. If less than 150, please continue with the remaining questions.

2.	Will a specific regulation have an adverse economic effect upon your business?			
	Yes	No	Explain: Please list each regulation	
	and explain the impa	act.		
3.	Will the regulation (s	s) have any beneficia	l effect upon your business?	
	Yes	No		
	Explain:			
4.	Do you anticipate any indirect adverse effects upon your business?			
	Yes	No		
	Explain:			
5.	Do you anticipate any indirect beneficial effects upon your business?			
	Yes	No		
	Explain:			

PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

CHAPTER 449

LCB File No. R096-08 and NAC Chapter 449

Surgical Centers for Ambulatory Patients

These regulation changes are being proposed in accordance with Assembly Bill 123, of the 2009 legislative session and to clarify certain requirements.

EXPLANATION – Matter *in italics* is new; matter in brackets [omitted material] is material to be omitted.

Section 1. Chapter 449 of NAC is hereby amended by adding thereto the provisions set forth as sections 4 to 8, inclusive, of this regulation.

- Sec. 2. "Acceptable Standards of Practice" defined. Acceptable standards of practice means standards of patient care for procedures, techniques and treatments that are based on research and/or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations.
- Sec. 3. "Certified First Assistant" defined. Certified First Assistant means a person that is certified as a surgical first assistant by the Association of Surgical Technologists.
- Sec. 4. "Independent Licensed Practitioner" defined. "Independent Licensed Practitioner" means a practitioner as defined in NRS 439A.0195.
- Sec. 5. "Medical Staff" defined. Medical staff means a physician and a physician assistant licensed in accordance with chapter 630 of NRS, or to practice osteopathic medicine pursuant to chapter 633, or a podiatrist licensed to practice pursuant to chapter 635, or a dentist

licensed to practice pursuant to chapter 631, or a surgical first assistant as defined in subsection 4, or a certified registered nurse anesthetist or advanced practitioners of nursing licensed to practice pursuant to chapter 632, that practices at the center.

Sec. 6. "Registered Nurse First Assistant" defined. A registered nurse first assistant means a person that is licensed to practice nursing pursuant to chapter 632 and that has completed a registered nurse first assistant program that meets the Association of Perioperative Registered Nurses (AORN) standard for a first assistant education program and is accepted by the Competency and Credentialing Institute.

Sec. 7. Each application for a license as a surgical center for ambulatory patients must comply with the requirements set forth in NRS 449.040. In addition to the requirements established in NRS 449.040, the applicant must provide evidence that the center has applied for accreditation with one of the entities described in section xx of these regulations.

Sec. 8. NAC 449.9741 is hereby amended to read as follows:

NAC 449.9741 "Physician" defined. "Physician" means a person who is licensed to practice medicine pursuant to chapter 630 of NRS or to practice osteopathic medicine pursuant to chapter 633 of NRS or to practice podiatric medicine pursuant to chapter 635 of NRS.

Sec. 9. NAC 449.9743 is hereby amended to read as follows:

NAC 449.9743 "Surgery" defined. "Surgery" means the treatment of a human being by a physician using one or more of the following procedures:

- Cutting into any part of the body using a scalpel, electrocautery or any other means for
 cosmetic enhancement or for diagnosis or the removal or repair of diseased or damaged
 tissue, organs, tumors or foreign bodies.
- 2. The reduction of a fracture or the dislocation of a bone, joint or bony structure.

- 3. The repair of a malformation of the body resulting from an injury, a birth defect or another cause, that requires cutting and manipulation or a suture.
- 4. An instrumentation of the uterine cavity of a woman for diagnostic or therapeutic purposes, including the procedure commonly known as dilation and curettage.
- 5. Any instrumentation of, or injection of a substance into, the uterine cavity of a woman to terminate a pregnancy.
- 6. Any procedure to sterilize a human being.
- 7. An endoscopic procedure.
- 8. A laproscopic procedure.

Sec. 10. NAC 449.9745 is hereby amended to read as follows:

NAC 449.9745 Compliance with requirements by accreditation. The operator of an ambulatory surgical center shall within 6 months after a license is issued by the Division, become accredited by one of the following accrediting organizations: the Joint Commission on Accreditation of Health Care Organizations, the Accreditation Association for Ambulatory Health Care or the American Association for Accreditation for Ambulatory Surgery Facilities.

[be deemed by the Division to have complied with the requirements for licensing contained in NAC 449.971 to 449.996, inclusive, if:

- 1. The center is currently accredited by the Joint Commission on Accreditation of Health Care Organizations, the Accreditation Association for Ambulatory Health Care or the American Association for Accreditation for Ambulatory Surgery Facilities;
- 2. The operator provides the Division with evidence of the accreditation; and
- 3. The standards for accreditation applied by the accrediting organization are at least as stringent as the requirements of NAC 449.971 to 449.996, inclusive.]

Sec. 11. NAC 449.9755 is hereby amended to read as follows:

NAC 449.9755 Investigation of applicant and inspection of center. After it receives a properly completed and notarized application, accompanied by the appropriate fee, the Division shall conduct an *on-site inspection of* [investigation of the applicant and inspect the] proposed center.

Sec. 12. NAC 449.979 is hereby amended to read as follows:

1. NAC 449.979 Governing body required. [Except as otherwise provided by NAC 449.9835;] 1. Except as provided in subsection 2, each ambulatory surgical center must have a governing body, chaired by a principal in the organization of the licensee, with legal authority for the operation of the center.

2. If a licensee is a single physician operator, the ambulatory surgical center operated by the licensee is required to establish a program for review of surgical procedures and patient outcomes, including the facility's program for the control and prevention of infections, and the rates of infections occurring in the center, through an outside resource that has no financial ties to the ambulatory surgical center.

Sec. 13. NAC 449.9795 is hereby amended to read as follows:

NAC 449.9795 Duties of governing body.

The governing body shall:

- 1. Adopt a set of rules which include provisions concerning:
 - (a) The criteria by which the members and officers of the governing body are selected, their terms of office and their duties;
 - (b) The frequency of its meetings; and
 - (c) The annual revision and approval of the rules by the governing body.

- 2. Arrange for minutes of its meetings to be taken to record the business conducted. These minutes must be available to all members.
- 3. When services are provided through an outside resource, the governing body shall establish how the services are coordinated with the center and how contracted personnel are to be supervised to ensure services are provided in a safe and effective manner.

Sec. 14. NAC 449.980 is hereby amended to read as follows:

NAC 449.980 Responsibilities of governing body. The governing body shall ensure that:

- 1. Each patient of the center is under the care of a physician.
- 2. Each patient admitted to the center receives a [presurgical evaluation] physical examination which includes the patient's medical history conducted by a physician or an independent licensed practitioner within 7 days immediately preceding the date of his surgery.
- 3. A physician is on the premises of the ambulatory surgical center and immediately available at all times when there are patients in the operating rooms or the recovery room of the center. As used in this subsection, "immediately available" means the physician is sufficiently free from other duties to be able to respond rapidly to an emergency.
- 4. An annual operating budget and a plan for capital expenditures are established.
- 5. The center is adequately staffed and equipped.
- 6. There is documentation in the files of the center of: [the]
 - (a) The qualifications and compliance with NAC 441A.375 of all persons employed by or under contract with the center; and

- (b) Whether such persons who work at the center and have exposure to patients have been screened for communicable diseases as described in NAC 441A.375.
- 7. The center establishes and maintains a program for the prevention and control of infections and communicable diseases as required pursuant to section 14 of this regulation.
- 8. The center adopts, enforces and at least annually reviews written policies and procedures required by NAC 449.971 to 449.996, inclusive, and sections 2 to 19, inclusive, of this regulation, including an organizational chart. These policies and procedures must:
 - (a) Be approved annually by the governing body.
 - (b) Provide that a surgical procedure may be performed on a patient only with the consent of the patient or his legal representative, except in an emergency.
 - (c) [Include procedures for the isolation or immediate transfer of a patient with a communicable disease.
 - (d)] Include procedures for the periodic review and amendment, as deemed appropriate, of the scope of the procedures performed at the center.

Sec. 15. NAC 449.9905 is hereby amended to read as follows:

NAC 449.9905 Pharmacist required; records, storage, medications and administration of drugs.

- A pharmacist must be on the staff of each ambulatory surgical center or under contract with the center. The pharmacist is responsible for all matters pertaining to the use of drugs in the center.
- 2. The pharmacist shall establish policies and procedures including, but not limited to:
 - (a) Storage of medications,
 - (b) Administration of medications to patients

- (c) Procedures for discharging patients with ordered medications in hand
- (d) The proper procedures for disposition or destruction of expired or contaminated medications pursuant to state law.

3. The pharmacist shall:

- (a) Visit the center at least once each month to evaluate the effectiveness of the policies and procedures established pursuant to subsection 2 and to confirm that documentation of each transaction involving medications is maintained.
- (b) Document each visit.
- (c) Periodically audit the records of the center related to the dispensing of controlled substances to ensure compliance with all applicable state and federal laws.
- (d) Ensure that medications are provided, prepared and administered in a safe and effective manner in accordance with accepted standards of practice and in accordance with the manufacturer's instructions.
- [2-] (4) Records of all transactions must be in writing and maintained so the receipt and disposition of any drug may be readily traced.
- [3.] (5) Drugs requiring refrigeration must be stored in a locked refrigerator or a refrigerator in a locked room. [Food must not be stored in this refrigerator except for food used as a vehicle for the administration of drugs.]
- [4-] (6) In the absence of a full-time pharmacist, the director of nursing must be designated in writing as responsible for the control of dangerous drugs and controlled substances. [Substances listed as schedule II controlled substances pursuant to] Controlled substances as described in chapter 453 of NRS must be stored in a storage area with two locks. If a box is

used, it must be securely fastened and immovable. The keys or combinations to the locks must be accessible only to licensed health care professionals.

- [5.] (7) [Drugs may not be kept in stock after the expiration date on the label. Obsolete, contaminated or deteriorated drugs must be destroyed.] All drugs must be logged into and checked out of stock only by a licensed health care professional.
- (6.) (8) The ambulatory surgical center shall obtain a license to operate a pharmacy pursuant to chapter 639 of NRS.
- 9. Records for any schedule II controlled substance must be maintained pursuant to chapter 453 of NRS. The record must indicate the name of the patient, the name of the prescriber, the name of the controlled substance, the dose administered, and the balance of the substance remaining. A count must be completed of all such controlled substances at the beginning and the end of each shift by two licensed health care professionals. The count must be authenticated by two licensed health care professionals. If a discrepancy in the count cannot be corrected, the pharmacist must be notified immediately or not later than the next working day.

Sec. 16. NAC 449.9801 is hereby amended to read as follows:

NAC 449.9801 Procedures for granting privileges to members of the medical staff.

- 1. The governing body shall:
 - (a) Adopt criteria for granting privileges to members of the medical staff based upon the size and complexity of the services provided by the center.
 - (b) Ensure that an application to be accorded privileges or for the renewal of those privileges is processed in an expeditious manner.

- (c) Adopt procedures for verifying information contained in an application to be accorded privileges or for the renewal of those privileges. The procedures may include a requirement for the applicant to sign a statement granting immunity from liability to the center for actions taken to verify the information and attesting to the accuracy and completeness of the information contained in the application.
- 2. The procedures for granting privileges to members of the medical staff must be approved by the governing body.
- 3. An application to be accorded privileges at an ambulatory surgical center must include, without limitation:
 - (a) Information related to the educational and professional training of the applicant;
 - (b) An evaluation conducted by the applicant's peers concerning the quality of care provided by the applicant;
 - (c) Evidence that the applicant is licensed or certified to provide in this State the professional services for which the privileges are being requested;
 - (d) Evidence of any license required to be obtained by the applicant from the Drug Enforcement Administration;
 - (e) A description or list of the privileges being requested;
 - (f) Evidence that the applicant has privileges at a hospital licensed pursuant to NRS 449.037 to which a patient could be transferred.
 - [(f)] (g) Information obtained from the National Practitioner Data Bank as may be required by federal law; and
 - [(g)] (h) Such other information as may be required by the governing body, including, without limitation, information relating to:

- (1) Any claims filed against the applicant for professional liability;
- (2) The revocation, suspension or voluntary relinquishment of the applicant's license or certification to practice in this State, any other disciplinary action that has been taken against the applicant in his professional capacity and any limitations or conditions placed on the applicant's license or certification to practice in this State;
- (3) Complaints or reports of any adverse action filed against the applicant with a local, state or national professional society or occupational board;
- (4) Insurance for professional liability maintained by the applicant, including any circumstance under which an insurer has refused to issue such insurance to the applicant or cancelled the applicant's insurance;
- (5) The denial, suspension, limitation, termination or refusal to renew privileges accorded to the applicant at another medical facility;
- (6) The suspension or revocation of a license issued to the applicant by the Drug Enforcement Administration;
- (7) Any conviction for a criminal offense, other than a minor traffic violation; and
- (8) Any physical or mental condition of the applicant that would interfere with his ability to provide professional services, including alcohol or drug abuse.
- 4. A member of the medical staff who is applying for the renewal of his privileges must provide evidence that he is in compliance with the provisions of subsection 3 on the date of the application.
- 5. The ambulatory surgical center shall maintain a record of the privileges accorded to each member of the medical staff of the center. The record must include, without limitation:

- (a) The application to be accorded privileges at the center;
- (b) Each application for the renewal of those privileges;
- (c) Evidence of the verification of the information contained in the applications;
- (d) The privileges granted; and
- (e) Such other information as may be required by the governing body.
- 6. Privileges accorded to a member of the medical staff must be:
 - (a) Consistent with his professional experience and authorized scope of practice;
 - (b) For a limited time as specified by the governing body or a person or committee designated by the governing body; and
 - (c) Be reviewed periodically and revised as appropriate.

Sec. 17. NAC 449.9812 is hereby amended to read as follows:

NAC 449.9812 Program for quality assurance.

- 1. The administrator of an ambulatory surgical center shall establish a program for quality assurance for the center.
- 2. The program for quality assurance must include, without limitation:
 - (a) Periodic reviews of the clinical responsibilities and authority of the members of the staff.
 - (b) Periodic evaluations of members of the staff that are conducted by their peers.
 - (c) Procedures for the supervision of the professional and technical activities of the members of the staff.
 - (d) [Periodic evaluations that are conducted to determine whether the clinical and administrative policies of the center are cost-effective. The evaluations required by

this paragraph must not be limited to the cost effectiveness of the administrative policies of the center.

- {(e)} Procedures for identifying and correcting any problems or concerns that provide an opportunity for all members of the staff who are health care practitioners to participate in the program for quality assurance.
- [(f)] (e) Techniques for self-assessment that are required to be used by the members of the staff and provide for an examination of the manner in which care has been, is and will be provided and the quality of the care provided.
- [(g)] (f) Procedures for identifying and addressing any problems or concerns related to the care provided to patients using the medical records of the center and any other sources of data that may be useful to identify previously unrecognized concerns, and for assessing the frequency, severity and sources of suspected problems and concerns. The procedures must include, without limitation, procedures for assessing:
 - (1) The clinical performances of members of the staff who are health care practitioners;
 - (2) The standards used for the maintenance of medical records;
 - (3) The procedures used to control the quality of radiological, pathological, laboratory and pharmaceutical services provided by the center;
 - (4) The procedures used to control the quality of other professional and technical services provided by the center;
 - (5) The care and services provided by the extended recovery unit, if such a unit is operated by the center;
 - (6) The procedures used to control infection; and

- (7) The satisfaction of patients who have been treated at the center.
- [(h)] (g) The maintenance of a record of all fires and deaths that have occurred at the center and the transfer of all patients from the center to a hospital.
- [(i)] (h) Procedures for assessing any actions taken to correct identified problems or concerns and for determining whether the actions taken have achieved or sustained the desired result and, if not, why not.
- 3. The members of the professional and administrative staffs of the center shall:
 - (a) Understand, support and participate in the program for quality assurance; and
 - (b) Participate in the resolution of any problems and concerns identified pursuant to the procedures required by subsection 2.
- 4. The members of the staff who are health care practitioners shall participate in the development and application of the criteria used to evaluate the care provided at the center and the evaluation of any problems and concerns identified pursuant to the procedures required by subsection 2.
- 5. Activities conducted pursuant to the program for quality assurance must be reported to the appropriate members of the staff and to the governing body. The administrator of the center shall establish procedures for carrying out any recommendations of the governing body.
- 6. As used in this section, "health care practitioner" means a person who is licensed or certified to provide health care services in this State, including, without limitation, a physician, dentist, podiatrist, and registered or licensed practical nurse.

Sec. 18. NAC 449.9813 is hereby amended to read as follows:

NAC 449.9813 Committee for quality assurance.

- 1. The governing body shall establish a committee for quality assurance.
- 2. The committee must be composed of members of the staff who represent the various clinical and medical services provided by the center.
- The committee shall carry out the program for quality assurance established pursuant to NAC 449.9812.
- 4. The committee shall meet at least quarterly and document the minutes of the meetings.

 The results of the quality assurance action plan shall be made available for review.

Sec. 19. NAC 449.9855 is hereby amended to read as follows:

NAC 449.9855 Policies and requirements for personnel. (NRS 449.037)

- An ambulatory surgical center shall have written policies for the personnel employed at
 the center. These policies must be provided to each employee in the form of a manual and
 must include provisions concerning hours of work, grievances in connection with
 termination, vacation, sick leave and leaves of absence.
- 2. Each employee of the center must:
 - (a) Have a skin test for tuberculosis in accordance with <u>NAC 441A.375</u>. A record of each test must be maintained at the center.
 - (b) Within 10 days after the date of his employment, and periodically thereafter, be instructed in the control of infections, the prevention of fires, the safety of the patients, preparation in case of disaster, and the policies and procedures of the center.
- 3. A current and accurate personnel record for each employee of the center must be maintained at the center. The record must include, without limitation:
 - (a) A job description that:

- (1) Includes the duties and responsibilities of, and the qualifications required for, the position held by the employee; and
- (2) Is signed by the employee;
- (b) Evidence that the employee has obtained any license, certificate or registration and that is in a current status, and possesses the experience and qualifications, required for the position held by the employee;
- (c) An annual evaluation of the employee that is signed by the employee and his supervisor; and
- (d) Such health records as are required by chapter 441A of NAC; and
- (e) A signed statement indicating the employee has read and understands the provisions of NAC 449.971 to NAC 449.9981.

Sec. 20. NAC 449.9865 is hereby amended to read as follows:

NAC 449.9865 Medical staff.

- The medical staff of an ambulatory surgical center is answerable to the governing body
 for the quality of medical care provided to patients and for the ethical and professional
 practices of its members.
- 2. The governing body, or a person or committee designated by the governing body, shall appoint the members of the medical staff and grant, deny and withdraw the privileges to be accorded members of the medical staff as it deems appropriate. Appointments to the medical staff must be made in writing and must be documented in the records of the center.
- Each member of the medical staff must be qualified for the position to which he is appointed and the privileges which he is accorded.

- 4. 4 A roster of the surgical privileges of each member of the medical staff must be kept in the files of the operating room, specifying the privileges accorded him.
- 5. Each member of the medical staff shall perform only the surgical procedures or treatment modalities for which they have been granted privileges.
- [5.] 6. The governing body shall establish procedures for disciplining a member of the medical staff who fails to comply with the policies and procedures of the center, and for ensuring the physicians do not perform surgeries for which they have not been granted privileges.
- 7. Services provided must be within the scope and limitations set forth in the plan of treatment and may not be altered in type, amount, frequency or duration, except in the case of adverse reaction.
 - (a) Describe how the contracted personnel are to be supervised.
 - (b) Describe how services are coordinated with the primary agency.

Sec. 21. NAC 449.989 is hereby amended to read as follows:

NAC 449.989 Medical records: Contents. (NRS 449.037) The medical record of each patient must be complete, authenticated, accurate and current, and must include the following information:

- 1. A complete identification of the patient, including information on his next of kin and on the person or agency legally or financially responsible for him.
- 2. A statement concerning the admission and diagnosis of the patient.
- 3. The medical history of the patient.

- 4. Documentation that the patient has [been-given a presurgical evaluation] had a medical history and physical examination conducted by a physician or independent licensed practitioner within the 7 days immediately preceding the date of the patient's surgery.
- 5. Evidence of any informed consent given for the care of the patient.
- 6. Any clinical observations of the patient, such as the notes of a physician, a nurse or any other professional person in attendance. Such an entry must be signed by the person making the entry and include the title of that person.
- 7. Reports of all studies ordered, including laboratory and radiological examinations.
- 8. Confirmation of the original diagnosis, or the diagnosis at the time of discharge.
- 9. A report of any operation performed on the patient, prepared by the surgeon.
- 10. A description of the procedure followed in any administration of anesthesia to the patient.
- 11. A recovery report for the patient.
- 12. A summary of discharge, including, without limitation, the disposition of the patient and any recommendations and instructions given to the patient.
- 13. Documentation that a member of the nursing staff interviewed the patient within 72 hours after the patient was discharged from the center to determine the condition of the patient and whether the patient was satisfied with the services provided, and to receive any complaints or problems the patient may have.

Sec. 22. NAC 449.9902 is hereby amended to read as follows:

NAC 449.9902 Emergency equipment and supplies required.

- 1. An ambulatory surgical center must be equipped with:
 - (a) A cardiac defibrillator;
 - (b) A tracheostomy set[; and] or a cricothyroidotomy set

- (c) A crash cart with equipment and supplies as defined by the medical staff and reviewed annually.
- (d) If the center provides services to pediatric patients between 0 to 8 years of age, the center shall have all necessary emergency medical equipment and supplies to treat a pediatric patient as defined by the medical staff and reviewed annually.
- (e) If general anesthesia is provided at the center or if the center carries a triggering agent for malignant hyperthermia the center shall have a malignant hyperthermia cart with equipment and supplies as defined by the medical staff that is reviewed annually.
- (f) If the center provides general anesthesia it shall have the necessary equipment and supplies needed to manage difficult airways as specified by members of the medical staff.
- (g) [e] Such other emergency medical equipment and supplies as are specified by the members of the medical staff.
- 2. A person trained in the use of emergency equipment and in cardiopulmonary resuscitation advanced cardiac life support (ACLS) must be on the premises of the ambulatory surgical center and immediately available at all times when there is a patient in the center. If a pediatric patient, between the ages of 0 to 8 is present in the center, a person trained in pediatric advanced life support (PALS) shall be present in the center and immediately available at all times. A person with ACLS certification may fulfill this requirement. As used in this subsection, "immediately available" means that the person is sufficiently free from other duties to be able to respond rapidly to an emergency.

Sec. 23. NAC 449.992 is hereby amended to read as follows:

NAC 449.992 Pathological services.

- Pathology services must be provided by a staff pathologist or by a pathologist used as a consultant by the ambulatory surgical center. The pathologist must be licensed to practice in this State.
- 2. All material removed from a patient during surgery must be clearly labeled and examined microscopically as required by a pathologist. In the absence of a staff pathologist, written arrangements must be made to send tissues to a pathologist outside the center.
- A list of tissues that do not routinely require microscopic examination must be approved by a pathologist and made available to the laboratory and the members of the medical staff.
- 4. Reports of examinations of tissues must be [authenticated] signed or electronically signed by the examining pathologist.

Sec. 24. NAC 449.993 is hereby amended to read as follows:

NAC 449.993 Diagnostic radiological services.

- Each ambulatory surgical center shall maintain diagnostic radiological services or have such services immediately available to meet the needs of their patients. Whether these services are provided directly or by contract, personnel capable of supervising the performance of the services must be available.
- 2. If a center provides diagnostic radiological services directly, the center must have a full-time radiologist or a radiologist who works as a part-time consultant available to supervise the department of radiology and to interpret films.

- 3. Before operating any radiology equipment, each person operating radiology equipment must have evidence of meeting at least one of the requirements listed in a through g below: [Only a person designated as qualified by the radiologist may operate the equipment for X rays.] Only a physician may perform a fluoroscopy.
 - (a) Certification in Radiography by the American Registry of Radiologic

 Technologists, or
 - (b) Successful completion of a program of formal training in X-ray technology of not less than 24 months duration in a school approved by the Council on Education of the American Medical Association or by the American Osteopathic Association, or have earned a bachelor's or associate degree from an accredited college or university, or
 - (c) For those individuals whose training was completed prior to July 1, 1996, but on or after July 1, 1960: Successful completion of 24 full months of training and/or experience under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968.
 - (d) For those individuals whose training was completed prior to July 1, 1960:

 Successful completion of 24 full months of training and/or experience of which at

 least 12 full months were under the direct supervision of a physician who is

 certified in radiology by the American college of Radiology or who possesses

 qualifications which are equivalent to those required for such certification, and at

least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968, or

- (e) A physician, or
- (f) A podiatrist, or
- (g) A dentist, dental assistant or dental hygienist may perform dental X-rays.
- 4. [A radiological technician] A person qualified to operate radiology equipment pursuant to subsection 3 must be on duty or available within 15 minutes after being called while the center is open.
- 5. [Examinations by X ray] Diagnostic radiological examinations must be ordered by the physician responsible for the care of the patient, and the order must contain a concise statement of the reason for the examination. Reports of these examinations must be signed by the reporting physician. The original report must be filed in the medical records of the patient, and a copy of the report must be kept in the radiology department.
- 6. If radiological services are provided at the center the center shall ensure that:
 - (a) The radiological services, particularly ionizing radiology procedures, must be free from hazards for patients and staff.
 - (b) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients and staff. Shielding devices must be stored according to the manufacturer's recommendations.
 - (c) Periodic inspection of equipment must be made and hazards identified must be properly corrected. Equipment must be maintained according to manufacturer's instructions. Defective equipment must not be used until all repairs have been made and the equipment has been determined to be safe by an appropriate entity

- authorized by the manufacturer to perform maintenance inspections and/or equipment repairs.
- (d) Staff working with active radiology equipment must wear exposure meters or badge tests which must be checked periodically for amount of radiation exposure to each person.
- Sec. 25. NAC 449.9935 is hereby amended to read as follows:

NAC 449.9935 Operating and recovery rooms; endoscopy suite.

- 1. The operating and recovery rooms of an ambulatory surgical center must be used exclusively for surgical procedures.
- Except as otherwise provided in subsection 3, surgical procedures must be conducted in a class A, B or C operating room in accordance with chapter 9 of the *Guidelines for Design* and Construction of Hospital and Health Care Facilities, adopted by reference pursuant to NAC 449.0105.
- 3. If an ambulatory surgical center is licensed to perform only endoscopic procedures, such procedures may be conducted in an endoscopy suite in accordance with chapter 9 of the Guidelines for Design and Construction of Hospital and Health Care Facilities, adopted by reference pursuant to NAC 449.0105.
- 4. A registered nurse experienced in surgical procedures shall supervise the operating room.
- 5. Only a registered nurse may function as the circulating nurse in the operating room.
- 6. Any person serving in the role of a surgical first assistant must be a registered nurse first assistant, a certified first assistant, a physician, a physician's assistant or an advanced practice nurse. A podiatrist may serve as a first assistant in podiatry cases. A dentist, a dental assistant or a dental hygienist may assist with dental procedures.

- [6]. 7. The operating room must be equipped with:
 - (a) A system for making emergency calls;
 - (b) Oxygen;
 - (c) Mechanical ventilatory assistance equipment, including, without limitation, a manual breathing bag and a ventilator;
 - (d) Cardiac monitoring equipment;
 - (e) Laryngoscopes, airways and endotracheal tubes; there shall be a variety of sizes of scopes and tubes sufficient to meet the needs of the patient populations receiving services in the center; and
 - (f) Suction equipment.
 - 8. The recovery room shall meet the following:
 - (a) The center shall adopt a nationally recognized standard of practice for post anesthesia care that is approved by the Governing Body. The center shall maintain a copy of the standards at the center during all hours of operation and in a location which is available to staff at all times.
 - (b) Staffing requirements:
- 1. Phase one recovery: requires 2 registered nurses present in the recovery room at all times while a patient is present. At least one registered nurse must be trained in post anesthesia care and advanced cardiac life support. Additional registered nursing staff shall be present in the recovery rooms based on the acuity of the patients and the ability to safely care for patients.
- 2. Phase two recovery: requires at least 1 registered nurse present in the Phase 2 recovery area that is trained in post anesthesia care and advanced cardiac life support when a

patient is present. Additional staffing ratios are dependent on the acuity of the patients and the ability to safely care for patients.

- (c) A malignant hyperthermia cart, emergency crash cart, emergency pediatric supplies (if necessary) and difficult airway cart must be easily accessible to the recovery room. The recovery room shall have the necessary equipment and supplies to safely care for patients.
- [7] 9. If the operating team consists of persons who are not physicians, [such as a dentist, a podiatrist or a nurse], a physician must be on the premises and immediately available in case of an emergency. As used in this subsection, "immediately available" means the physician is sufficiently free from other duties to be able to respond rapidly to the emergency.

Sec. 26. NAC 449.9937 is hereby amended to read as follows:

NAC 449.9937 Extended recovery units.

- 1. An ambulatory surgical center may operate an extended recovery unit.
- 2. An extended recovery unit must:
 - (a) Be located in an area of the center that is separate from the other operations of the center;
 - (b) Provide audio and visual privacy for each patient in the unit;
 - (c) Be supervised by at least one physician who is recommended for the position by the members of the medical staff and approved by the governing body;
 - (d) Have at least one physician on the premises or immediately available by telephone at all times when there is a patient in the unit;
 - (e) Except as otherwise provided in paragraph (f), have at least one nurse who is trained in advanced cardiac life support on duty for every two patients in the unit;

- (f) Have at least two nurses who are trained in advanced cardiac life support on duty at all times when there is a patient in the unit; and
- (g) Be equipped with:
 - (1) A system for making emergency calls;
 - (2) Oxygen;
 - (3) A cardiac defibrillator;
 - (4) A manual breathing bag;
 - (5) Cardiac monitoring equipment
 - [(5)] (6) Suction equipment; and
 - [(6)]-(7) A crash cart with equipment and supplies as defined by the medical staff and reviewed annually; and
 - (8) Such other emergency equipment as is needed to provide care to patients in the unit.
- 3. A patient must be admitted and discharged from an extended recovery unit only upon the order of the physician of record. If a patient is admitted to the unit, the time he remains in the unit for treatment, when added to the time he remains in any other area of the ambulatory surgical center for treatment, may not exceed 23 hours and 59 minutes.
- 4. The center shall adopt policies and procedures for the extended recovery unit that include, without limitation:
 - (a) Clinical criteria for determining a patient's eligibility for admission into the unit;
 - (b) Clinical criteria for determining a patient's eligibility for being discharged from the unit:
 - (c) Procedures for providing emergency services; and

- (d) Procedures for transferring a patient in need of other health care services.
- 5. An ambulatory surgical center shall provide food to meet the needs of patients in an extended recovery unit. A patient on a special diet must be served food that conforms to the patient's prescribed diet. If the food is prepared by the center, the center shall:
 - (a) Comply with the applicable provisions of <u>chapter 446</u> of NRS and the regulations adopted pursuant thereto; and
 - (b) Obtain such permits as are necessary from the Bureau of Health Protection Services of the Health Division to prepare the food.

Sec 27. NAC 449.994 is hereby amended to read as follows:

NAC 449.994 Records required before surgery; report of surgery. (NRS 449.037)

- 1. [A presurgical evaluation] A medical history and physical examination completed within the 7 days immediately preceding the date of the patient's surgery [conducted] by a physician or licensed independent practitioner [and the pertinent past medical history of a patient] must be recorded in the chart of the patient before surgery.
- 2. A properly executed form of consent to surgery *pursuant to NRS 449.710(6)* must be placed in the medical record of the patient before surgery.
- 3. A report must be prepared immediately after surgery describing the *techniques*, [and] findings and tissues removed or altered of the surgery and signed by the surgeon.
- 4. The operating room register must be complete and current. The register includes at least the following information: patient's name, patient's center identification number, date of operation, name of the surgeon and ay assistants, the total time of the operation, type of anesthesia used and the name of all persons administering the anesthesia, operation performed, and the pre and post operative diagnosis.

Sec. 28. Is hereby amended to read as follows:

NAC 449.9945 Administration and record of anesthesia.

- Anesthetics must be administered in the operating room of an ambulatory surgical center
 by an anesthesiologist, a qualified physician, a dentist or, under the direction of the
 operating physician and in accordance with the provisions of chapter 632 of NRS and the
 regulations adopted pursuant thereto, a certified registered nurse anesthetist.
- Persons designated to administer anesthetics must be qualified to administer anesthetics based on their credentials and must be approved by the governing body.
- 3. General anesthesia must not be administered to a patient unless a physician has evaluated the patient immediately before surgery to assess and document the risks of administering the anesthesia relative to the surgical procedure to be performed. A patient who receives general anesthesia must be evaluated by a physician after the patient has recovered from the general anesthesia and before he is discharged from the recovery room.
- 4. A record of anesthesia must be completed after surgery, and there must be a follow-up on each patient who has received anesthesia with the findings recorded by the person who administered the anesthesia.
- 5. As used in this section, "certified registered nurse anesthetist" has the meaning ascribed to it in NRS 632.014.
- (6) Anesthesia provider, including providers of conscious sedation, deep sedation, general anesthesia, must constantly monitor the patient and have no other responsibilities. The provider must not leave the patient unless relieved by another qualified provider licensed pursuant to NRS 632, ----that assumes care of the patient.

Sec. 29. NAC 449.996 is herby amended to read as follows:

NAC 449.996 Transfer of patients.

- 1. Each ambulatory surgical center shall maintain with a licensed general hospital a written agreement concerning the transfer of patients. The agreement must provide for the security of, and the accountability for, the personal effects of the patient.
- 2. If a patient is transferred, all medical and administrative information relating to the patient must be transferred with him or promptly made available to the licensed center or agency responsible for his continuing care.
- 3. The center shall establish written guidelines for patient transfers and arrangement for ambulance services for the immediate transfer to a hospital for patients requiring emergency medical care beyond the capabilities of the center. The guidelines shall be approved by the Governing Body.